K100645

Medtronic

SEP 14 2012

510(k) Summary

Date Prepared:	April 8, 2011
Submitter:	Medtronic, Inc. 7611 Northland Drive Minneapolis, MN 55428 Establish Registration Number: 2184009
Contact Person:	Jessica Sixberry Senior Regulatory Affairs Specialist Phone: (763) 514-9849 Fax: (763) 367-8360 Email: jessica.m.sixberry@medtronic.com

Device Name and Classification:

Trade Name:	Affinity Pixie™ Oxygenation System with Carmeda® BioActive Surface or Balance™ Biosurface		
Common Name:	Oxygenator, cardiopulmonary bypass	Blood Reservoir, cardiopulmonary bypass	Thermometer, Electronic, Clinical
Regulation Number:	21 CFR 870.4350 21 CFR 870.4240	21 CFR 870.4400 21 CFR 870.4270 21 CFR 870.4230	21 CFR 880.2910
Product Code:	DTZ, DTR	DTN, JOD, DTP	FLL
Classification:	Class II	Class II	Class II

Predicate Devices

Medtronic AFFINITY NT® Oxygenator with Carmeda (K000430)
Medtronic AFFINITY NT Oxygenator with Trillium (K973760)
Medtronic Minimax® Plus Oxygenator with Carmeda (K933586)
Medtronic AFFINITY NT Cardiotomy/Venous Reservoir with Trillium (K021287)
Medtronic Minimax Cardiotomy/Venous Reservoir (K911789)
Medtronic Thermistor Probe (K831528)
Terumo Capiox RX05 Oxygenator with and without Reservoir (K022115)

Device Description

The Affinity Pixie Oxygenation System with Carmeda BioActive Surface or Balance Biosurface is a system that includes an oxygenator, cardiotomy/venous reservoir (CVR), and temperature probe.

The oxygenator is a single use, sterile, nonpyrogenic fluid path oxygenator to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during cardiopulmonary bypass procedure up to 6 hours in duration.

The reservoir is a single use device designed to collect and store blood during extracorporeal circulation. Cardiotomy blood is collected, filtered, and defoamed before mixing with the filtered venous blood. The reservoir can also be used for vacuum-assisted venous drainage.

The temperature probe is a reusable device for use with the temperature monitoring adapter of compatible Medtronic devices and the YSI™ Telethermometer. The probe has a thermistor sensor housed in a stainless steel sheath connected to a 3 m (10 ft) shielded cable, terminating with a 7 mm (1/4 in) phono plug.

Product Family	Model	Description
Oxygenator only	CBP211	Affinity Pixie Hollow Fiber Oxygenator with Carmeda BioActive Surface
	BBP211	Affinity Pixie Hollow Fiber Oxygenator with Balance Biosurface
Oxygenator with CVR	CBP241	Affinity Pixie Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Carmeda BioActive Surface
	BBP241	Affinity Pixie Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface
Temperature probe	ATP210	Affinity Temperature Probe

Indications for Use

Oxygenator: The Affinity Pixie Hollow Fiber Oxygenator (with Carmeda or Balance coating) is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Reservoir: The Affinity Pixie Cardiotomy/Venous Reservoir (with Carmeda or Balance coating) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

Temperature Probe: The Affinity Temperature Probe is intended for use for continuous blood temperature monitoring as measured at a temperature monitoring adapter located within a Medtronic extracorporeal circulation device as specified in the device's Instructions for Use. The Temperature Probe is designed for use with a YSI™ Tele-thermometer to monitor and display temperature.

Conclusion

Medtronic has demonstrated that the Affinity Pixie Oxygenation System is substantially equivalent to the predicate devices based upon design, test results, and indications for use.

Comparison to Predicate Devices

The Affinity Pixie Oxygenator System has the same intended use, design and materials, and principles of operation and technology when compared to the predicate devices.

Oxygenator

- Intended Use: The Affinity Pixie Oxygenator has the same intended use as the current Affinity NT oxygenator. The intended patient population (neonate/infant/child) is the same population as the predicate Terumo and Minimax Plus devices.
- Design and Materials: The design and the materials of the Affinity Pixie Oxygenator and the predicate devices are essentially the same. The design of each device is similar in that they each contain a heat exchanger for temperature control, and an oxygenator for gas transfer. Such a design is common among oxygenating devices on the market. The devices are manufactured with various plastics, adhesives, urethanes, polypropylene, etc. The Affinity Pixie device is available in two coating options, Carmeda and Balance both of which are biocompatible surface coatings that increase the thromboresistance of the blood contact surfaces. Carmeda is an available coating on the predicate Affinity NT Hollow Fiber Oxygenator. Balance is a heparin free version of Trillium coating. Balance is available on the Affinity Pixie Arterial Filter. Trillium coating is available on the Affinity Hollow Fiber Oxygenator.
- Principles of Operation and Technology: The technology of the subject device and the predicate devices (Affinity NT and Terumo) are essentially identical. Blood is pumped into the heat exchanger device whereby blood temperature is controlled with the use of essentially a water bath. After the blood exits the heat exchanger, it enters the oxygenator device whereby gas transfer occurs (i.e., introduction of oxygen; removal of carbon dioxide). The transfer process occurs via diffusion across the walls of the hollow fiber membranes contained within the oxygenator.
- Performance: Comparisons of the performance of the Affinity Pixie Oxygenator and the predicate devices were conducted. The comparisons demonstrated that there were no significant performance differences between the devices.

Cardiotomy/Venous Reservoir

- Intended Use: The Affinity Pixie Cardiotomy/Venous Reservoir has the same intended use as the current Affinity NT CVR with the addition of the vacuum assisted venous drainage (VAVD) which is included in the Terumo indications statement. The intended patient population (neonate/infant/child) is the same population as the Terumo and Minimax reservoir.
- Design and Materials: The design and the materials of the Affinity Pixie Cardiotomy/Venous Reservoir and the predicate devices are essentially the same. The design of each device is similar in that they each contain a reservoir for collection of blood that addresses both cardiotomy and venous blood. The devices are manufactured with variations of plastics, adhesives, urethanes, etc. The Affinity Reservoir is available in Trillium coating. The Pixie reservoir is available in both

Carmeda and Balance coatings, which both provide a thromboresistant surface to the blood contact surfaces of the device.

- Principles of Operation and Technology: The technology of the subject device and the predicate devices (Affinity NT and Terumo) are essentially identical. The devices operate in a manner where blood is collected into the reservoir. The blood may enter the reservoir via the venous inlet or the cardiotomy inlet. The reservoirs each contain filtering/defoaming devices that facilitate the removal of particulate matter and air. The Affinity Pixie Cardiotomy/Venous Reservoir may be used in procedures that utilize Vacuum Assist procedures to facilitate blood flow into the hardshell reservoir in the same manner of the Terumo Capiox Reservoir which includes vacuum assist in their intended use.
- Performance: Comparisons of the performance of the Affinity Pixie Cardiotomy/Venous Reservoir and the predicate devices were conducted. The comparisons demonstrated that there were no significant performance differences between the devices.

Temperature Probe

- Intended Use: The Affinity Temperature Probe is intended for use for continuous blood temperature monitoring as measured at a temperature monitoring adapter located within a Medtronic extracorporeal circulation device as specified in the device's Instructions for Use. The Temperature Probe is designed for use with a YSI™ Tele-thermometer to monitor and display temperature.
- Design and Materials: The design and the materials of the Affinity Temperature Probe and the predicate device are the same.
- Principles of Operation and Technology: The technology of the subject device and the predicate devices are identical. The temperature probe is inserted into an adapter port where it interfaces with the temperature monitoring adapter.
- Performance: Testing was completed to ensure that the Affinity Temperature Probe measures temperature within the specified accuracy per the performance requirements.

Summary of Performance Data

Bench and animal testing were used to demonstrate the performance characteristics of the Pixie oxygenation system. Clinical testing was not required to establish substantial equivalence. The following special controls documents were utilized for testing guidance:

- Guidance for Cardiopulmonary Bypass Oxygenators (Nov 13, 2000)
- Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA (Nov 29, 2000)
- Guidance on the Content of Premarket Notification [510(k)] Submission for Clinical Electronic Thermometers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 14 2012

Medtronic, Inc.
c/o Jessica Sixberry
Senior Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, MN 55428

Re: K100645
Trade Name: Affinity Pixie Oxygenation System with Carmeda or Balance Biosurface
Regulation Numbers: 21 CFR 870.4350; 870.4240; 870.4400; 870.4270; 870.4230; and 880.2910
Regulation Names: Cardiopulmonary Bypass Oxygenator; Cardiopulmonary Bypass Heat Exchanger; Cardiopulmonary Bypass Blood Reservoir; Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter; Cardiopulmonary Bypass Defoamer; Clinical Electronic Thermometer
Regulatory Class: II
Product Codes: DTZ; DTR; DTN; JOD; DTP; FLL
Dated: March 4, 2010
Received: March 5, 2010

Dear Ms. Sixberry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K100645

Device Name: Affinity Pixie Oxygenator System with Carmeda Bioactive Surface or Balance Biosurface

Indications for Use:

Oxygenator: The Affinity Pixie Hollow Fiber Oxygenator with Carmeda BioActive Surface or Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Cardiotomy Venous Reservoir: The Affinity Pixie Cardiotomy/Venous Reservoir with Carmeda BioActive Surface or Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

Temperature Probe: The Affinity Temperature Probe is intended for use for continuous blood temperature monitoring as measured at a temperature monitoring adapter located within a Medtronic extracorporeal circulation device as specified in the device's Instructions for Use. The Temperature Probe is designed for use with a YSI™ Tele-thermometer to monitor and display temperature.

Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K100645